FIRST REGULAR SESSION

HOUSE BILL NO. 37

92ND GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVES JOHNSON (47) AND SALVA (Co-sponsors) .

Pre-filed December 2, 2002, and copies ordered printed.

TED WEDEL, Chief Clerk

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AN ACT

To amend chapter 208, RSMo, by adding thereto seven new sections relating to the Missouri Rx card program, with an emergency clause.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 208, RSMo, is amended by adding thereto seven new sections, to be known as sections 208.585, 208.587, 208.589, 208.591, 208.593, 208.595 and 208.597, to read as follows:

208.585. 1. As used in sections 208.585 to 208.597, the following terms shall mean:

- 2 (1) "Department", the Missouri department of social services;
- 3 (2) "Director", the director of the Missouri department of social services;
- 4 (3) "Labeler", an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages such drugs for later retail sale, and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. Section 207.20;
 - (4) "Manufacturer", a manufacturer of prescription drugs, as defined in 42 U.S.C. Section 1396r-8(k)(5), including a subsidiary or affiliate of a manufacturer;
 - (5) "Participating retail pharmacy", a retail pharmacy or other business licensed to dispense prescription drugs in this state that participates in the state Medicaid program or voluntarily agrees to participate in the Missouri Rx card program;
- 13 (6) "Wholesaler", a business licensed pursuant to chapter 338, RSMo, to distribute 14 prescription drugs in this state.
 - 208.587. 1. There is hereby established within the department of social services the
- 2 "Missouri Rx Card Program" as a state pharmaceutical assistance program under 42
- 3 U.S.C. Section 1396r-8(c)(1)(C)(i)(III) to provide discounts to participants for drugs

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4 covered by a rebate agreement established in section 208.589. Using sums from negotiated rebates, the department shall contract with wholesalers or participating retail pharmacies to deliver discounted prices to the Missouri Rx card participants.

- 2. The drug discounts received by Missouri Rx card participants shall be calculated by the director on a quarterly basis. Such calculation shall provide discounts approximately equal to the amount of the negotiated drug rebate minus an amount to cover the reasonable administrative costs of the Missouri Rx card program.
- 3. Except as otherwise provided for in subsection 4 of this section, any person who is a resident of this state and is eligible for participation in the Medicare program or has a net family income below three hundred percent of the federal poverty level is eligible to participate in the Missouri Rx card program.
- 4. A person shall be ineligible to participate in the Missouri Rx card program if such person is eligible for assistance under the state's Medicaid program or is covered by an insurance policy that provides benefits for prescription drugs equal to or greater than the benefits provided under the Missouri Rx card program, as delineated by rules promulgated by the department.
- 5. The department shall establish simple procedures for enrolling Missouri Rx card participants and shall implement outreach efforts to increase public awareness of the program and maximize enrollment by eligible residents.
- 208.589. 1. The director shall negotiate discount prices or rebates for prescription drugs from drug manufacturers and labelers. A drug manufacturer or labeler that sells prescription drugs in this state may voluntarily elect to negotiate:
- (1) Supplemental rebates for the Medicaid program over and above those required under 42 U.S.C. Section 1396r-8;
 - (2) Discount prices or rebates for the Missouri Rx card program; and
- (3) Discount prices or rebates for any other state program that pays for or acquires prescription drugs.
 - 2. In negotiating rebate terms, the director shall take into consideration:
- 10 (1) The rebate calculated under the Medicaid rebate program pursuant to 42 U.S.C. Section 1396r-8; 11
 - (2) The price provided to eligible entities under 42 U.S.C. Section 256b; and
- (3) Any other available information on prescription drug prices, discounts, and 14 rebates.
- 15 3. (1) The director shall initiate a review of whether to place a manufacturer's or 16 labeler's products on the prior authorization list for the state Medicaid program and take similar actions involving prior authorization or formularies for any other state-funded or 17

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operated prescription drug program if: 18

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- (a) The director and a drug manufacturer or labeler fail to reach agreement on the 20 terms of a supplemental Medicaid rebate or a discount or rebate for the Missouri Rx card program; and
- 22 (b) The discounts or rebates offered by the manufacturer or labeler are not as 23 favorable to the state as the prices provided to eligible entities under 42 U.S.C. Section 24 256b.
- (2) Any prior authorization shall meet the requirements of 42 U.S.C. Section 1396r-26 8(d)(5) and this chapter. The director shall promulgate rules establishing clear procedures for the implementation of this section.
 - (3) The names of manufacturers and labelers that do not enter into rebate agreements are public information. The department shall release such information to the public and actively distribute such information to its physicians, pharmacists, and other health care professionals.
 - 208.591. 1. The department shall adopt rules requiring disclosure by participating retail pharmacies to the Missouri Rx card program participants of the amount of savings provided as a result of the program. Such rules shall protect information that is proprietary in nature.
 - 2. A participating retail pharmacy shall verify to the department the amounts charged to Missouri Rx card program participants and nonparticipants, and shall provide the department with utilization data necessary to calculate rebates from manufacturers and labelers. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule, or regulation. department shall not impose transaction charges on wholesalers or participating retail pharmacies that submit claims or receive payments under the program.
 - 3. Wholesalers and participating retail pharmacies shall be paid in advance for Missouri Rx card discounts or shall be reimbursed by the department on a weekly basis.
 - 4. The department may require a wholesaler or participating retail pharmacy to segregate drugs under the Missouri Rx card program from other drug inventory. The department may require a wholesaler or participating retail pharmacy to maintain records of acquisition and disposition of drugs under the Missouri Rx card program separately from the wholesaler's or pharmacy's other records.
- 208.593. 1. Disputes or discrepancies in rebate amounts shall be resolved using the process established in this section. 2
 - 2. If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler,

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the department, at the department's expense, may hire a mutually agreed upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

- 3. If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or provide a refund to the manufacturer or labeler.
- 4. Following the procedures established in subsections 2 and 3 of this section, either the department or the manufacturer or labeler may request a hearing. Supporting documentation shall accompany the request for a hearing.
- 208.595. 1. The department shall report the enrollment and financial status of the Missouri Rx card program and report savings from supplemental Medicaid rebates to the general assembly by February first of each year.
 - 2. The director may combine drug pricing negotiations to maximize drug rebates if the director finds that it is beneficial to both the Missouri Rx card program and another state program, including the state Medicaid program.
 - 3. The department shall adopt rules to implement the provisions of sections 208.585 to 208.597. No rule or portion of a rule shall become effective unless it has been promulgated pursuant to the provisions of chapter 536, RSMo.
- 4. The department may seek waivers of federal law, rule, or regulation necessary to implement the provisions of sections 208.585 to 208.597.
- 208.597. The provisions of sections 208.585 to 208.597 shall become effective on 2 July 1, 2003, and discounts to participants in the Missouri Rx card program shall begin by 3 January 1, 2004.

Section B. Because immediate action is necessary to provide adequate pharmaceutical treatment for the residents of this state section A of this act is deemed necessary for the immediate preservation of the public health, welfare, peace, and safety, and is hereby declared to be an emergency act within the meaning of the constitution, and section A of this act shall be in full force and effect on July 1, 2003, or upon its passage and approval, whichever later occurs.